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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,238	03/02/2002	Rong Xiang	TSRI 830.0	6584

7590 11/18/2003

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,238	XIANG ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *2,6,7,14,19 and 21-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5, 8-13, 16-18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-35 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 1, 3-5, 8-9, 10-13,16-18 and 20 with species of bacterial vector Salmonella typhimurium in Paper No. 6 is acknowledged.

2. The requirement is deemed proper and is therefore made FINAL.

3. Applicants are reminded to amend the claims 1, 3-5, 8-9, 10-13,16-18 and 20 in the scope of bacterial Salmonella typhimurium vector for reflecting the examination on the merits.

4. Claims 2, 6-7, 14-15, 19 and 21-35 are withdrawn from the consideration. Applicants are reminded to cancel the claims dawn to the non-elected groups.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 10 and 16-18 are rejected under 35 U.S.C. 102(a) as anticipated by Xiang et al. (J. Immunol. 2001, Vol. 167, pp. 4560-4565).

7. Xiang et al. disclose several DNA plasmid constructs comprising a sequence encoding carcinoembryotic antigen (ECA), or CD40 ligand trimer (CD40LT) or ECA/CD40LT. Each plasmid is further packaged into the attenuated Salmonella typhimurium bacterial vector and formulated as a DNA vaccine composition and delivered orally into the CEA-transgenic C57BL/6J mice to see the immune response against murine colon adenocarcinama challenge, wherein the colon cancer cell line is transfected with CEA (MC38-ECA-KSA). They found that the composition comprising both ECA and CD40LT has more significant inhibitory effect against the tumor growth (See entire document, especially sections of materials and Methods on page 4561 and Results on page 4562) than that of the plasmid only comprising CD40LT or CEA antigen along. they concluded that co-immunization of mice with the dual function of DNA

vaccine encoding both CD40LT and CEA un-regulates the CTL activity markers, increases expression of costimulatory molecules and enhances the production of cytokines. Therefore, the antigen specific CTL responses are increased (See results on pages 4662 and 4564). Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 3-5, 8-13, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiang et al. (J. Immunol. 2001, Vol. 167, pp. 4560-4565) and Weiner et al. (WO 99/43839A1).

10. Regarding to claims 1, 10 and 16-18, Xiang et al. disclose DNA vaccine constructs comprising a carcinoembryotic antigen (ECA), CD40 ligand trimer (CD40LT) or ECA/CD40LT inserted into different plasmids respectively. Each plasmid is further packaged into the attenuated Salmonella typhimurium bacterial vector and formulated as a DNA vaccine composition and is delivered orally into the CEA-transgenic C57BL/6J mice to see immune response against murine colon adenocarcinama cell line transfected with CEA (MC38-ECA-KSA) challenge. They found that the DNA vaccine comprising both ECA and CD40LT has more significant inhibitory effect against the tumor growth (See entire document, especially sections of materials and Methods on page 4561 and Results on page 4562) than that of the plasmid only comprising CD40LT or CEA antigen. While Xiang et al. do not teach to construct the CD40LT and CEA as separate plasmids and use as separate plasmids, they concluded that co-immunization of mice with the dual function of DNA vaccine encoding both CD40LT and CEA un-regulates the CTL activity markers, increases expression of costimulatory molecules

and enhances the production of cytokines. Therefore, the antigen specific CTL responses are increased (See results on pages 4662 and 4564).

11. However, regarding to claims 3-5, 8-9, 12-13 and 20 related to construct the CD40LT and CEA into two separate plasmids, Weiner et al. teach a composition and a method of using the composition to induce an immune response in an individual against the immunogen, wherein the composition comprises two plasmids, the first plasmid encoding a cancer-associated antigen and the second plasmid encoding a nucleotide sequence of an immunomodulating protein of CD40L (Claims 19-24). They concluded that increased antigen-specific Th cell proliferation, INF-λ production as well as CTL response were achieved by co-injection plasmid DNAs encoding CD40 ligand (See lines 6 on page 70 through line2 on page 71).

12. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated to construct the CD40LT and ECA genes into two separate plasmids in light of the disclosure of Weiner et al. and further package the plasmids into the Salmonella T bacterial vector, and administer them simultaneously into the animals to get a same immune protective response as compared with that of using one plasmid comprising both CD40LT and ECA as taught by Xiang et al. Because the selection f constructing CD40LT and CEA separately into two plasmids or together into one plasmid is only a designed choice. The control element of getting a good anti-tumor protective immune response as taught by Xiang et al. is to co-administer both CD40TL and CEA simultaneously no matter they are present in the same plasmid or in two plasmids. As long as the animals receiving the CD40LT and CEA at the same time, the animals will get a significantly protective immune response against the CEA positive tumor growth than that receiving the CD40LT or CEA immunization along.

13. Regarding to the claim 11 related to use the composition in human, because Xiang et al. and Weiner et al. already teach every element of the claimed DNA composition and a method of using the composition to achieve best anti-tumor protective immune response in animal, it would have been obvious for a person with ordinary skill in the art to be motivated to use the DNA composition comprising both CD40LT and CEA in human to see the immune response.

14. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li November 12, 2003

JAMES HOUSEL 11/17/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600